1648

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Application of:**

Pau et al.

**Serial No.:** 09/722,867

**Filed:** November 27, 2000

**For:** PRODUCTION OF VACCINES

**Confirmation No.:** 4248

**Examiner:** L. Scheiner

**Group Art Unit:** 1648

**Attorney Docket No.:** 2578-4626US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

10/06/2004
Date

Betty Vowles
Signature

Betty Vowles
Name (Type/Print)

## PETITION TO MAKE SPECIAL UNDER M.P.E.P. §§ 708.02 VII AND X

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Special Program Examiner for Group Art Unit 1648

Sir:

**Petition**

Applicants petition to make the above-referenced application related to HIV/AIDS and recombinant DNA special.

**Requirements under M.P.E.P. § 708.02 X**

A statement explaining how the invention contributes to the diagnosis, treatment or prevention of HIV/AIDS is transmitted herewith.

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**Requirements under M.P.E.P. § 708.02 VII**

A statement under 37 C.F.R. § 1.102 by the assignee explaining the relationship of the invention to safety of research in the field of recombinant DNA research is transmitted herewith.

**Fee**

The fee required under 37 C.F.R. § 1.17(h) for each basis of the petition is to be paid by the attached check for $260.00. If the attached check is insufficient to cover the fees related to this petition, please charge any overage to Deposit Account 20-1469.

**REMARKS**

Consideration of this petition is respectfully requested.

Respectfully submitted,

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Date: October 6, 2004
AFN
Document in ProLaw

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10/06/2004 Betty Vowles
Date Signature

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**STATEMENTS SUPPORTING PETITION TO MAKE SPECIAL UNDER M.P.E.P. §§ 708.02 VII AND X**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Special Program Examiner for Group Art Unit 1648

Sir:

**Statement concerning HIV/AIDS**

The above-referenced application contributes to the treatment and prevention of HIV/AIDS in that "the invention is useful for the production of vaccines to aid in the protection against viral pathogens for vertebrates, such as mammals." (Specification, page 1, lines 8-9). Furthermore, the specification recites "other viral proteins (subunits) and viruses (wt to be inactivated) or attenuated viruses that may be produced in the methods according to the invention include ... retrovirus, such as human immunodeficiency virus." (*Id.* at page 15, line 24 through

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page 16, line 3). Thus, the present invention relates to the prevention of HIV/AIDS in that it eases the production of materials used for diagnostic and research purposes.

**Statement concerning recombinant DNA**

The above-referenced application relates to safety of research in the field of recombinant DNA research as it enhances the safety of vaccines and vaccine production. More specifically, the as-filed specification indicates "for safety reasons care is best taken to avoid unnecessary adenoviral sequences in the cells. It is thus another embodiment of the invention to provide cells that do not produce adenoviral structural proteins." (*Id.* at page 14, lines 21-23).

As further stated in the specification "to have a clean and relatively safe production system from which it is easy to recover and, if desirable, to purify the virus, it is preferred to have a method according to the invention, wherein, the human cell comprises no other adenoviral sequences." (*Id.* at page 14, line 25 through page 15 line 1). The specification also indicates "importantly, any non-human system for producing influenza vaccines has an inherent drawback, known as 'adaption'. Human influenza A and B virus both carry mutations in the HA, due to adaptation in embryonated hens' eggs. These mutations result in altered antigenicity. ... In humans, immunization with vaccines containing HA bearing an egg-adaption mutation induces less neutralizing antibody to virus than a non-egg adapted HA." (*Id.* at page 6, lines 18-24). Thus, the present invention relates to the field of safety in recombinant DNA technology.

Ronald H.P. Brus, President & CEO, Crucell Holland BV.